CGA M-6—2013

GUIDELINE FOR ANALYTICAL METHOD VALIDATION

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

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1 Introduction

Analytical methods for testing medical gases are described in medical gas monographs contained in the *United States Pharmacopeia* and *National Formulary (USP–NF)* [1].[1] These analytical methods are called compendial methods. When using a test method other than a compendial method, a firm has to demonstrate (validate) that the test method it is using is equivalent to the corresponding compendial method. In addition, if a firm is performing release testing on a medical gas that is not defined in the compendia, the test method must also be validated to demonstrate that it is appropriate for its intended used. This publication includes information on:

- developing a validation protocol;
- challenge gases;
- conducting a validation study;
- data analysis;
- acceptance criteria;
- final report content;
- record retention;
- method suitability under actual conditions of use; and
- gas chromatography (GC) system suitability.

2 Scope

This publication describes the minimum requirements for validating noncompendial analytical test methods. It also describes a method for establishing the equivalency of alternate test methods.

This publication is intended to meet the requirements of:

- Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 211.165(e), 211.194(a)(2), and 820.72(a) [2]; and
- Chapter 1225 (Validation of Compendial Methods) and portions of Chapter 621 (Gas Chromatography) in the *USP–NF* [1].

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Alternate test method
Analytical method that is not an official compendial method provided a compendial method exists.

NOTE—Alternate methods are also called noncompendial methods.

3.2 Challenge gas
Gas of known quality used to perform analytical validations.

3.3 Compendia
Collection of monographs established by the *USP–NF* for drugs and drug ingredients/excipients [1].

3.4 Compendial test method
Analytical method contained or referenced in a *USP–NF* monograph [1].

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.